

## **REMARKS**

Claims 1-30 remain pending in this application.

Claim 11 has been withdrawn pending allowance of a generic claim.

Claims 1, 20, 22, and 29 are in independent form.

Claims 1, 20, 22, and 29 have been amended to recite additional distinguishing features.

Support for the added “spherically adjacent” and “anterior and posterior” language can be found in Figures 2 and 5 and at page 6, lines 26 to page 7, line 5. Support for the faster/slower absorbability or degradation rate can be found on page 7, lines 8-10 and on page 9, line 15.

Support for the surface-smoothing and irritation-reducing language may be found on page 4, line 8-11.

### **Rejection Under 35 USC 102**

Applicant respectfully traverses the rejection of Claim 20 in view of Ragheb et al.

The reference does not disclose an anchoring coating or a second coating portion spherically adjacent to the first coating portion exhibiting surface-smoothing and irritation-reducing properties as now recited in the Claims. Ragheb’s bioactive layers 18 and 18' are drug dispensing strata with no anchoring function or capability.

Moreover, Ragheb does not disclose an orbital implant as recited in the body of the claims at issue.

The rejection of Claims 1-10 and 12-30 in view of Perry is also traversed because the reference does not disclose two anchoring coating portions spherically adjacent to each other and exhibiting different absorbability rates.

### **Rejection Under 35 USC 103**

The purposes of the instant invention are:

- a) To facilitate insertion of the implant (p 4, l 9-11) and cover surface spicules(p 2, l 14-15 and p 4, l 9-10);
- b) To provide a stable, temporary anchoring of muscles to the implant (p 4, l 11);
- c) To promote fibrovascular ingrowth (p 4, l 12-13); and,
- d) To strike a balance between the divergent anchoring and ingrowth promoting goals.

The solution is provided by covering separate areas of the implant surface by surface-smoothing and irritation-reducing coatings to which outer muscular tissue can be attached having different degradation rates; whereby the posterior, faster degrading coating will allow early fibrovascular ingrowth into the core of the implant while the later degrading coating will maintain anchoring for a longer period.

Applicant submits that none of the Buscemi et al., Ragheb et al. and Mc Ghan prior art references teaches anything towards that solution. The only tenuous relevancy that can be attributed to these references is that they disclose implants having portions with different degradation rate.

Buscemi et al. is a temporary stent designed to maintain the structural integrity of a tubular vessel that can safely dissolve without creating a risk of emboli.

Ragheb et al. discloses a drug delivery implant which carries different drugs to be released at different rates.

McGhan, combines the features of Buscemi et al. and Ragheb et al. by providing a stent with different drug delivering capabilities.

Surface smoothing and irritation reduction are not within the purposes or functions of these

references.

The anchoring and vascularization functions and their syncretization is nowhere taught or even in issue in these references. Accordingly, no inference of obviousness of the claimed invention could be drawn from these references or their combination with the other cited prior art.

In fact, the Examiner has relied on several odd combinations of references that applicant submits are not warranted by what they disclose.

#### Perry and Buscemi et al. Combination

Perry discloses a permanent intra-orbital implant covered by an absorbable, synthetic coating formulated to allow for the free formation of fibrovascular tissue. (p.12, l.29, 35; p.14, l.7)

Buscemi et al. discloses a temporary, bio-absorbable stent with two functions: a) internal support of a tubular vessel in order to facilitate flowthrough; and b) slow delivery of a drug. The stent is formed of several layers of different degradability materials.

There would be no motivation to combine the permanent implant of Perry covered by anchoring and vascularization-enhancing coatings with the temporary stent of Buscemi et al. that is not intended for permanent attachment with surrounding tissue or to enhance through vascularization.

The first function of the stent is to facilitate flowthrough of blood or other liquid in the vessel. The reference goes as far as shaping the inner walls of the stent to prevent eddies and other disruptions of the inner flow (C.7, l.27-31). This function is contrary to the main purpose of Perry and of the instant invention which is to favorize attachment of musculature to the implant and its supply of nutrients by vascularization through the outer coating.

The second function of the stent is to deliver a combination of drugs at different rates. This purpose is also claimed in secondary claims by Perry, but only to deliver preparations that enhance adhesion and vascularization, a goal contrary to Buscemi. The variable bioabsorption rates of the various layers or parts of the stent are calculated to control and release of the drugs (C.12, l.19-32) and not different rates of vascularization.

Far from motivating their combination, the Perry and Buscemi et al. references are oddly conflicting and at cross-purpose.

#### Perry and Ragheb et al. Combination

For the same reasons given in connection with the Perry/Buscemi et al. combination, the Perry/Ragheb et al. combination is neither suggested by the references nor coherent. Ragheb et al. discloses the graded release of drugs imbedded in coatings of different biodegradable materials surrounding a stent or other implant. There is no teaching of smoothing the surface of the implant or favoring anchoring or vascularization of the implant through the biodegradable coatings. The most that can be gathered from this reference, as from Buscemi et al., is that materials of different rates of bioabsorbability may be combined in one device. The main purpose of the coating is to distribute the drugs at graduated rates not to provide an anchor for sutures, allow access to fibrovascular ingrowth, enhance fluid flow toward the implant and facilitate insertion as was sought in Perry and in the instant invention, all this at different rates for separate sections of the implant.

There was no motivation to combine Ragheb et al. with Perry when looking for a means to favorize ingress of tissue into the implant since the former is designed to exude substances out of the implant.

The respective purposes of the references are counter-intuitive.

#### Perry and McGhan Combination

McGhan discloses two superimposed bioabsorbable layers 41 and 101 around a prosthetic implant. Their purposes are to prevent adhesion to a surrounding capsule (C.7, L.42-50) by creating surface roughness by way of irregularly shaped absorbable particles (C.4, L.14-20).

Each layer is textured by contour irregularities designed to disorient structural proteins within the capsule (C.7, L.31-35).

In Perry and in the instant invention, the coating is formulated to encourage adhesion and vascular ingrowth of the surrounding tissue and to form a smooth outer surface that facilitates insertion. McGhan's asperities would make insertion more difficult if not impossible.

Applicant cannot envision any motivation to combine these references or to look at McGhan as a solution to the problems he faced in the design of his implant. Indeed McGhan would defeat the main purposes sought by Perry.

#### Combination of Vachet with either Buscemi et al., Ragheb, et al. or McGhan

Vachet discloses covering an orbital implant with a permanent, micro-porous skin that permit colonization by the natural surrounding tissue. There would be no logic in combining the permanent skin of McGhan with any one of the biodegradable coatings of the other three references.

Moreover, there is no compatibility between the ingrowth promoting skin and the drug diffusing coatings. Nowhere in the references are the combinations suggested or inferred.

The most that can be gleaned from the cited references and their various combinations is that

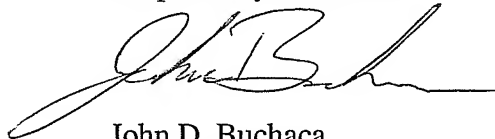
layers of different bio-absorption rates may be used in the fabrication of implants in order to release substances into the surrounding tissues at different rates and times, and not to provide different rates and attachment. Furthermore, the reference teaches the use of a single type of implant cover material instead of the multiple material coating taught by the invention.

The Examiner's use of incongruous combinations of references falls short of establishing obviousness.

The very incongruity of the asserted combinations constitutes a compelling evidence of the non-obviousness of the claimed invention. In others this incongruity is a powerful indicator that, on balance, the differences between the claimed structure and those element disclosed in the cited reference would not be obvious to one of ordinary skill in the orbital implant art.

In view of which an early allowance of all the pending claims is earnestly solicited.

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